



**UNITED STATES DEPARTMENT OF COMMERCE**  
**Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/260,037	03/02/99	YACOBY-ZEEVI	0 910/13

HM12/1221

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EXAMINER

HUTSON, R

ART UNIT	PAPER NUMBER
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1652

14

DATE MAILED:

12/21/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Advisory Action

Application No.  
09/260,037

Applicant(s)  
Yacoby-Zeevi

Examiner  
Richard Hutson

Group Art Unit  
1652



THE PERIOD FOR RESPONSE: [check only a) or b)]

- a) ☒ expires 4 months from the mailing date of the final rejection.
- b) ☐ expires either three months from the mailing date of the final rejection, or on the mailing date of this Advisory Action, whichever is later. In no event, however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

- ☐ Appellant's Brief is due two months from the date of the Notice of Appeal filed on \_\_\_\_\_ (or within any period for response set forth above, whichever is later). See 37 CFR 1.191(d) and 37 CFR 1.192(a).

Applicant's response to the final rejection, filed on Nov 29, 2000 has been considered with the following effect, but is NOT deemed to place the application in condition for allowance:

- ☒ The proposed amendment(s):
- ☐ will be entered upon filing of a Notice of Appeal and an Appeal Brief.
- ☒ will not be entered because:
- ☒ they raise new issues that would require further consideration and/or search. (See note below).
- ☒ they raise the issue of new matter. (See note below).
- ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
- ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: Applicants amendment drawn to a prep for use in vivo comprising ex vivo cells... introduces new 112 issues as the claim is indefinite and confusing and raises a question as to whether the specification provides support for the limitation to "ex vivo".

- ☐ Applicant's response has overcome the following rejection(s):

- ☐ Newly proposed or amended claims \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claims.

- ☒ The affidavit, exhibit or request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See attached sheet.

- ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

- ☒ For purposes of Appeal, the status of the claims is as follows (see attached written explanation, if any):

Claims allowed: \_\_\_\_\_

Claims objected to: \_\_\_\_\_

Claims rejected: 1-8

- ☐ The proposed drawing correction filed on \_\_\_\_\_ ☐ has ☐ has not been approved by the Examiner.

- ☐ Note the attached Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

- ☒ Other Int. Summaries 13:14

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### **DETAILED ACTION**

Claims 1-53 are pending.

#### ***Claim Rejections - 35 USC § 102***

Claims 1 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Fuks et al. (US Pat No: 5,362,641).

The rejection is stated in the previous office action. This rejection is maintained in light of non-entry of applicants amendment.

Claims 1, 2, 4 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by the Sigma Catalog (page 275, 1992).

The rejection is stated in the previous office action. This rejection is maintained in light of non-entry of applicants amendment.

#### ***Claim Rejections - 35 USC § 103***

Claims 1-5, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuks et al. and Wang et al. (J. Orthop. Res., 14 (2): 149-153 1996, abstract).

This rejection is stated in the previous office action.

Applicants further traverse this rejection on the basis that one of ordinary skill in the art would be motivated to add heparanase in vivo so as to cause the release of the beneficiary growth factors thereat and that one would not be motivated to add heparanase ex vivo because such addition would result in the reverse action, ie., depletion of the factors from the biological preparation. This argument is not found persuasive because it is not believed that the treatment

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of bone grafts prior to implantation of the grafts in recipient bone tissue with heparanase as opposed to basic fibroblast growth factor would result in the depletion of the growth factors from the graft tissue as proteins released from cells within the graft would remain within the graft.

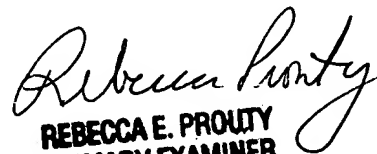
Further as was stated in the original rejection, one of ordinary skill in the art at the time of filing would have been motivated to pretreat bone grafts prior to implantation of the grafts in recipient bone tissue with heparanase to start the release of FGF. This is considered an ex vivo preparation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on M-F from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapy Achutamurthy (Murthy), can be reached on (703) 308-3804. The fax number for Official Papers to Technology Center 1600 is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Richard Hutson Ph.D.  
12/19/2000

  
**REBECCA E. PROUTY**  
**PRIMARY EXAMINER**  
**GROUP 1800-**  
**1600**